

REMARKS

Claims 15-25, 27-30, 32 and 34-52 are pending in this application. Claims 15, 18-21, 25, 27-30, 32 and 34-36 have been amended. Claims 1-14 have been canceled as drawn to nonelected subject matter. Claims 26, 31 and 33 have been canceled. New Claims 37-52 have been added. Support for the amendments and new claims is found in the specification and claims as filed.

Claim Rejections - 35 U.S.C. § 102(b) - Lord et al.

Claims 15-17, 22-25, 26-29, and 33 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. 5,569,186 (hereinafter "Lord et al."). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." See, e.g., *In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Lord et al. does not disclose every element of Applicants' claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(b).

Claims 26 and 33 have been canceled. Accordingly, the rejection is moot as to those claims.

Pending Claim 15, from which Claims 16, 17, 22-24, 27, and 28 depend, recites an integrated system comprising, *inter alia*, "a medicament delivery device, wherein the delivery device is physically detachably connectable to the receiver." Lord discloses a closed loop infusion pump system with removable glucose sensor including a sensor unit 16, a monitor 28 and an infusion pump 14. The infusion pump of Lord et al. is not "physically detachably connectable" from the monitor 28 (identified as a "receiver" in the Office Action). Likewise, if the infusion pump controls that can be housed within the monitor 28 (See Lord et al., col. 4, lines 1-5) are also considered a part of the infusion pump, these controls are likewise not "physically detachably connectable" from the monitor 28. Accordingly, Lord et al. does not disclose "a medicament delivery device, wherein the delivery device is physically detachably connectable to the receiver" as recited in Claim 15.

Pending Claim 25, which has been amended into independent form to incorporate the language of Claim 15 as filed, has also been amended to recite an integrated system for monitoring and treating diabetes comprising, *inter alia*, "a medicament delivery device, wherein the medicament delivery device comprises a cell transplantation device" and "a processor,

wherein the processor comprises programming configured to determine a host's metabolic response to cell transplantation by evaluating the sensor data points substantially corresponding to delivery or release of cells." Lord et al. neither teaches nor suggests such a configuration, and includes no teaching or suggestion of a cell transplantation device or programming configured to determine a host's metabolic response to cell transplantation by evaluating the sensor data points substantially corresponding to delivery or release of cells. Accordingly, Lord et al. does not disclose "a medicament delivery device, wherein the medicament delivery device comprises a cell transplantation device" or "a processor, wherein the processor comprises programming configured to determine a host's metabolic response to cell transplantation by evaluating the sensor data points substantially corresponding to delivery or release of cells" as recited in Claim 25.

Pending Claim 29, which has been amended into independent form to incorporate the language of Claim 15 as filed, has also been amended to recite an integrated system for monitoring and treating diabetes comprising, *inter alia*, "a single point glucose monitor, wherein the single point glucose monitor is integral with the receiver." Lord et al. neither teaches nor suggests such a configuration, in that the monitor 28 does not include a single point monitor integral therewith. Accordingly, Lord et al. does not disclose "a single point glucose monitor, wherein the single point glucose monitor is integral with the receiver" as recited in Claim 29.

As discussed above, Lord et al. does not disclose every element of Applicants' Claims 15, 25, and 29, as well as their corresponding dependent claims. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) - Lord et al. in view of Connelly et al.

Claims 18 and 21 have been rejected under 35 U.S.C. §103(a) as obvious over Lord et al. in view of U.S. Patent No. 6,589,229 ("Connelly et al."). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

Claims 18 and 21 depend from Claim 15. As discussed above, Lord et al. does not teach or suggest an integrated system comprising “a medicament delivery device, wherein the delivery device is physically detachably connectable to the receiver.” Connelly et al. teaches that it is known to practice daily insulin therapy with syringes and/or pumps, but, as in Lord et al, a “delivery device [that is] physically detachably connectable to the receiver” is neither taught nor suggested.

Because Lord et al. does not teach or suggest all the limitations of pending Claims 18 and 21, and because Connelly et al. does not include any teaching overcoming the deficiencies of Lord, a *prima facie* case of obviousness cannot be established. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. § 103(a) - Lord et al. in view of Mitragotri et al.

Claim 19 has been rejected under 35 U.S.C. §103(a) as obvious over Lord et al. in view of U.S. Patent No. 5,814,599 (“Mitragotri et al.”). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. See M.P.E.P. § 2143.

Claim 19 depends from Claim 15. As discussed above, Lord et al. does not teach or suggest an integrated system comprising “a medicament delivery device, wherein the delivery device is physically detachably connectable to the receiver.” Mitragotri et al. teaches the use of a transdermal patch to administer insulin to a diabetic patient, but, as in Lord et al., a “delivery device [that is] physically detachably connectable to the receiver” is neither taught nor suggested.

Because Lord et al. does not teach or suggest all the limitations of pending Claim 19, and because Mitragotri et al. does not include any teaching overcoming the deficiencies of Lord, a *prima facie* case of obviousness cannot be established. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. § 103(a) - Lord et al. in view of Mullins et al.

Claim 20 has been rejected under 35 U.S.C. §103(a) as obvious over Lord et al. in view of U.S. Patent No. 3,219,533 (“Mullins et al.”). To establish a *prima facie* case of obviousness,

three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

Claim 20 depends from Claim 15. As discussed above, Lord et al. does not teach or suggest an integrated system comprising “a medicament delivery device, wherein the delivery device is physically detachably connectable to the receiver.” Mullins et al. teaches an inhaler that sprays insulin for treating diabetes, but, as in Lord et al., a “delivery device [that is] physically detachably connectable to the receiver” is neither taught nor suggested.

Because Lord et al. does not teach or suggest all the limitations of pending Claim 20, and because Mullins et al. does not include any teaching overcoming the deficiencies of Lord, a *prima facie* case of obviousness cannot be established. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. § 103(a) - Lord et al. in view of Yamaguchi et al.

Claim 30 has been rejected under 35 U.S.C. §103(a) as obvious over Lord et al. in view of U.S. Patent No. 4,927,516 (“Yamaguchi et al.”). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

Claim 30 depends from Claim 29. As discussed above, Lord et al. does not teach or suggest an integrated system for monitoring and treating diabetes wherein, *inter alia*, the integrated single point glucose monitor is “integral with” the receiver. Yamaguchi et al. teaches an enzyme sensor that is able to sense glucose in a patient, but, as in Lord et al., “a single point glucose monitor, wherein the single point glucose monitor is integral with the receiver” is neither taught nor suggested.

Because Lord et al. does not teach or suggest all the limitations of pending Claim 30, and because Yamaguchi et al. does not include any teaching overcoming the deficiencies of Lord et

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al., a *prima facie* case of obviousness cannot be established. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. § 103(a) - Lord et al. in view of Mann et al.

Claims 31-32 and 34-36 have been rejected under 35 U.S.C. §103(a) as obvious over Lord et al. in view of U.S. Patent No. 7,025,743 ("Mann et al."). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

Claim 31 has been cancelled. Accordingly, the rejection is moot as to this claim.

Pending Claim 32, which has been amended into independent form to incorporate the language of Claims 15 and 31 as filed, has also been amended to recite an integrated system for monitoring and treating diabetes wherein, *inter alia*, the "processor" comprises "a validation module comprising programming configured to validate the medicament delivery instructions prior to outputting the instructions." As noted in paragraph 30 of the Office Action, Lord et al. fails to specifically disclose a receiver with a microprocessor and programming. Mann et al. teaches an infusion device including a receiver for receiving remotely generated commands. However, Mann et al. neither teaches nor suggests a processor that comprises "a validation module comprising programming configured to validate the medicament delivery instructions prior to outputting the instructions."

Pending Claim 34, which has been amended into independent form to incorporate language of Claims 15 and 33 as filed, has also been amended to recite an integrated system for monitoring and treating diabetes wherein, *inter alia*, the "processor" comprises programming "configured" to determine a host's metabolic response to the medicament delivery by evaluating the sensor data points substantially corresponding to delivery and release of the medicament delivery for the first time period. As noted in paragraph 30 of the Office Action, Lord et al. fails to disclose a receiver with a microprocessor and programming. Mann et al. neither teaches nor suggests a processor that comprises "programming configured to determine a host's metabolic

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response to the medicament delivery by evaluating the sensor data points substantially corresponding to delivery and release of the medicament delivery for the first time period.”

Because Lord does not teach or suggest all the limitations of pending Claim 32 or 34, and because Mann does not include any teaching overcoming the deficiencies of Lord, a *prima facie* case of obviousness cannot be established for independent Claims 32 and 34 or their corresponding dependent claims. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 2/6/07

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